DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2014

Intuitive Surgical Incorporated
Ms. Melissa S. Gonzalez
Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K141077
Trade/Device Name: daVinci Firefly Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GCJ, IZI
Dated: July 15, 2014
Received: July 16, 2014

Dear Ms. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141077

Device Name
da Vinci Firefly Imaging System

Indications for Use *(Describe)*
The da Vinci® Firefly™ Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.
Fluorescence imaging of biliary ducts with the da Vinci Firefly Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Melissa S. Gonzalez Regulatory Affairs Phone Number: 408-523-8684 Fax Number: 408-523-8907 Email: melissa.gonzalez@intusurg.com
Date Summary Prepared:	April 24, 2014
Trade Name:	*da Vinci*® *Firefly*™ Imaging System
Common Name:	Endoscopic instrument control system, endoscopic instruments and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	*da Vinci*® *Xi* Surgical System device, K131861 *da Vinci*® Fluorescence Imaging Vision System, K101077 *da Vinci*® Fluorescence Imaging Vision System, K124031

Device Description

The Intuitive Surgical *da Vinci*® *Firefly*™ Imaging System uses the existing endoscopic imaging system as submitted in K131861 (cleared March 28, 2014) for high definition (HD) visible light and near-infrared fluorescence imaging during minimally invasive surgery. The *da Vinci*® *Firefly*™ Imaging System utilizes the following existing components of the *da Vinci Xi* Surgical System:

- 8 mm 0° and 30° endoscopes (PNs 470026 and 470027)
- Endoscope Controller (PN 372601)

For near-infrared fluorescence imaging, the Fluorescence Imaging Kit is also required. The kits will be provided to the end user in an identical manner to the current supply and distribution chain for the predicate device. The kit is unchanged from K101077 (February 4, 2011)/K124031 (September 13, 2013).

- Fluorescence Imaging Kit (PN 950156) [Includes IndoCyanine Green (ICG) fluorescence imaging agent, aqueous solvent, and syringe trays]

Intended Use/Indications for Use:

The *da Vinci*® *Firefly*™ Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci Firefly* Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the *da Vinci Firefly* Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Technological Characteristics:

In terms of intended use, indications for use, and technological characteristics, the *da Vinci*® *Firefly*™ Imaging System is substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device, cleared under K131861, and the *da Vinci* Fluorescence Imaging Vision System (K101077) with modified indications cleared under K124031. There is one minor change to the internal glue used within the endoscope (non-patient-contacting) which does not substantively change the function of the subject device relative to the function of the predicate device.

Performance Data:

Performance test data (bench and animal tests) demonstrate that the subject device is substantially equivalent to the predicate devices and that the design output meets the design input requirements for fluorescence imaging. The testing conducted consisted of bench and animal testing, and a human factors assessment.

Bench Testing

The testing provided in this submission consisted of dimensional measurements, mechanical, and functional verification.

Test	Summary
Design Verification – All final tests PASSED	The purpose of this test was to verify that the endoscopes met the dimensional, mechanical, functional, and electrical requirements and specifications. Test methods were based on pre-defined test procedures, and objective pass/fail criteria were defined in the protocol and used. Sample sizes up to 5 units were used. The following design verification tests were performed: - Optical - Illumination - Mechanical - Environmental - Labeling

Animal Testing

The testing provided in this submission was performed using simulated clinical models (animal) to evaluate the performance of the *da Vinci Firefly* Imaging System (endoscopes and endoscope controller). This included design validation to confirm the device meets the user needs and intended use, comparison testing against the predicate device (IS3000 Firefly), and surgeon evaluations.

Test	Summary
Design Validation – All final tests PASSED	The purpose of this testing was to confirm that the *da Vinci Firefly* Imaging System meets the user needs and intended use as documented in the Product Requirements document. Testing was completed across two labs conducted with one canine and one porcine. A variety of surgical tasks were completed to evaluate the Firefly mode performance characteristics. Test methods were based on pre-defined test procedures and objective pass/fail criteria were defined in the protocol and used.
Device Comparison – All final tests PASSED	This testing compared the basic clinical function of the *da Vinci Firefly* Imaging System with respect to the predicate device (IS3000 Firefly mode). The study was a side-

Test	Summary
	by-side comparison of fluorescence image quality between the two systems. Two porcines were both used in a nephrectomy setup and an upper GI setup to complete various visualization tasks for each system.
Surgeon Evaluation – All final tests PASSED	The purpose of this testing was to confirm that the *da Vinci Firefly* Imaging System has clinically acceptable performance and allows for safe and effective surgical use as assessed by independent, external surgeon evaluators. Testing was completed across four labs, utilizing canines or porcines. Four independent, external surgeons served as evaluators to complete the vision assessments. All evaluators completed at least one Firefly application to assess the various Firefly vision parameters.

Human Factors and Usability Testing

A comprehensive Human Factors Engineering (HFE) process for the development of the IS4000 Firefly was conducted in accordance with the following FDA guidelines:

- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, 2000
- Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011

The human factors development process focused primarily on identifying critical tasks and ensuring the safe and effective use of the product. User experience with the predicate device, the IS3000 *da Vinci* Surgical System Firefly (IS3000 Firefly), helped identify and assess use-related risks for the IS4000 Firefly.

A Summative usability validation study was conducted with 16 teams of users (surgeons and operating room staff) for the *da Vinci*® *Firefly*™ Imaging System. The study was conducted in a simulated operating room and involved typical workflow scenarios, as well as certain troubleshooting scenarios related to safety-critical tasks. Results of the validation studies and the other elements of the human factors engineering program provided evidence that the *da Vinci*® *Firefly*™ Imaging System is safe and effective when used by the intended users in the intended use environment.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the *da Vinci® Firefly*™ Imaging System is substantially equivalent to the currently marketed *da Vinci Xi* Surgical System device, cleared under K131861, and the *da Vinci* Fluorescence Imaging Vision System (K101077) with modified indications cleared under K124031.